

The purpose of this amendment is to:

1. Post Questions and Answers (provided as a separate attachment).
2. Revise Section 1.2 – BAA Open Period to “This BAA will remain open from 18 July 2016 through 14 October 2016, 1400 Eastern Daylight Time (EDT). Phase I Proposals must be received by this time and date in order to be considered. Submission information is provided in Section 3.3 of this BAA.”
3. Revise Section 6.0 – Estimated Milestones to the following:

MILESTONE SCHEDULE	DATE
BAA Posted to FBO	18 Jul 2016
Begin registration at the DTRA proposal submission website	18 Jul 2016
DTRA proposal submission website opens for receipt of Quad Chart/White Paper	18 Jul 2016
Deadline to submit questions	9 Sep 2016
Questions and Answers posted at FBO	23 Sep 2016
Phase I Proposal receipt deadline	14 Oct 2016
Phase II Proposals invited	01 Dec 2016
Phase II Proposal receipt deadline	06 Jan 2017
Announcement of Apparent Successful Phase II Offerors; non-selection notifications will follow within two weeks (“on or about” is used since this is an estimate)	06 Mar 2017
Estimated First Award Date (“on or about” is used since this is an estimate)	04 Aug 2017 ^{1, 2}

Notes:

1: Actual award dates will vary based on complexity, statutory requirements, quality of proposal, pricing considerations, DCAA audits of proposed rates, type of instrument, number of awards, and other considerations. All dates are subject to change.

2: Awards will be made subject to the availability of funds.

4. Revise Section 7.1 – List of Topics, Topic CBA-02 – “**Objective**” to the following:

Objective: This topic seeks proposals that leverage known biomarkers of exposure to CWAs into assays for employment in any of the following contexts: (a) minimally invasive assays for high levels of exposure to long latency cholinesterase-inhibiting agents for which medical intervention could change the outcome; and (b) low burden trigger to treat for presumptively exposed personnel without objective signs of exposure in high threat scenarios. Assays should be applicable to multiple CWAs of current concern. The goal is to develop low-cost, FDA-cleared assays applicable to determining exposure to chemical warfare agents in a battlefield setting. This topic will ultimately support the JPEO MCS Diagnostics program to develop field diagnostic tests for chemical warfare agents.

Offerors shall address the following in their technical approach:

- A clear roadmap to FDA approval of a field assay for CWAs with 7 years, with clearly defined and measureable quantitative go/no-go decision points subject to validation by government-defined entities external to the performing team.
 - Articulate consideration of how the assay would be applied within a field setting relevant to one or multiple of the contexts described above, including realistic limitations of such application(s).
 - A robust plan for translation from appropriate in vitro and in vivo models to human relevance, as well as translation from any experiments which may initially employ chemical warfare agent simulants to those which employ the actual agents at appropriate facilities.
 - A plan and appropriate partnerships to enable translation of successfully demonstrated assays to either current commercial platforms [8-10] or new platforms which will be commercialized.
- This topic is NOT seeking efforts which are focused purely on: new biomarker discovery, laboratory-based analysis or forensics methods, or computational modeling.

Offerors are encouraged to develop R&D collaborations with other organizations in Government, academia, and the private sector to broaden and strengthen their knowledge, experience and capabilities. Additionally, offerors are encouraged to take advantage of specialized resources in the DoD and other Government agencies such as facilities/capabilities.